



Clinical trial results:

Open-Label, Multi-Center, Phase 2 Study of Anti-CCR4 Monoclonal Antibody KW 0761 (mogamulizumab) in Subjects with Previously Treated Peripheral T-cell Lymphoma (PTCL)

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2011-004151-39 |
| Trial protocol | GB DE ES DK NL |
| Global end of trial date | 22 July 2015 |

Results information

| | |
|--------------------------------|----------------|
| Result version number | v1 (current) |
| This version publication date | 13 August 2016 |
| First version publication date | 13 August 2016 |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | 0761-007 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01611142 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Kyowa Hakko Kirin Pharma, Inc. |
| Sponsor organisation address | 212 Carnegie Center, Suite 101, Princeton, United States, NJ 08540 |
| Public contact | Clinical Trial Information, Kyowa Hakko Kirin Pharma, Inc., 001 6099191100, KKD.KW-0761@kyowakirin.com |
| Scientific contact | Clinical Trial Information, Kyowa Hakko Kirin Pharma, Inc., 001 6099191100, KKD.KW-0761@kyowakirin.com |

Notes:

Paediatric regulatory details

| | |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 16 December 2015 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 22 July 2015 |
| Global end of trial reached? | Yes |
| Global end of trial date | 22 July 2015 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To determine the overall response rate of KW-0761 for the treatment of subjects with relapsed or refractory PTCL

Protection of trial subjects:

The study was conducted in accordance with the principles of the Declaration of Helsinki, the International Conference on Harmonization (ICH) consolidated guideline E6 - Good Clinical Practice (GCP) and any applicable national and local laws and regulations. Subjects were provided with written and oral information about the study (aims, methods, anticipated benefits, potential hazards and insurance arrangements). No procedures were conducted until informed consent was provided. The protocol included wording for the treatment of skin rash and hypersensitivity-like reactions (wording regarding premedication prior to KW-0761 infusion was also included in the protocol).

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 06 June 2012 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | Netherlands: 4 |
| Country: Number of subjects enrolled | Spain: 5 |
| Country: Number of subjects enrolled | United Kingdom: 8 |
| Country: Number of subjects enrolled | Denmark: 2 |
| Country: Number of subjects enrolled | France: 15 |
| Country: Number of subjects enrolled | Italy: 4 |
| Worldwide total number of subjects | 38 |
| EEA total number of subjects | 38 |

Notes:

Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 | 0 |

| | |
|---------------------------|----|
| months) | |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 23 |
| From 65 to 84 years | 14 |
| 85 years and over | 1 |

Subject disposition

Recruitment

Recruitment details:

Recruitment opened in May 2012 and closed in October 2013.

Pre-assignment

Screening details:

All subjects were screened for eligibility to participate in the trial. Subjects that met all inclusion/exclusion criteria as per protocol, were eligible for entry into the study. A total of 59 subjects were screened of which 21 failed the screening process. 38 patients were therefore enrolled into the study.

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|--|---------------------------------------|
| Arm title | Mogamulizumab (KW-0761) |
| Arm description: - | |
| Arm type | Experimental |
| Investigational medicinal product name | Mogamulizumab (KW-0761) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

1.0mg/kg over at least 1 hr on Days 1, 8, 15 and 22 of the first cycle and Days 1 and 15 of each subsequent 28-day cycle.

| Number of subjects in period 1 | Mogamulizumab (KW-0761) |
|--------------------------------|-------------------------|
| Started | 38 |
| Completed | 35 |
| Not completed | 3 |
| Adverse event, non-fatal | 1 |
| Patient discretion | 2 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|---------------|
| Reporting group title | Overall study |
|-----------------------|---------------|

Reporting group description: -

| Reporting group values | Overall study | Total | |
|---|---------------|-------|--|
| Number of subjects | 38 | 38 | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 23 | 23 | |
| From 65-84 years | 15 | 15 | |
| 85 years and over | 0 | 0 | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 57.7 | | |
| full range (min-max) | 19 to 87 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 15 | 15 | |
| Male | 23 | 23 | |

End points

End points reporting groups

| | |
|--------------------------------|-------------------------|
| Reporting group title | Mogamulizumab (KW-0761) |
| Reporting group description: - | |

Primary: Number of patients achieving overall response

| | |
|------------------------|--|
| End point title | Number of patients achieving overall response ^[1] |
| End point description: | |

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Disease response was assessed every 8 weeks.

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Descriptive analysis was utilised for this primary endpoint.

| | | | | |
|-----------------------------|-------------------------|--|--|--|
| End point values | Mogamulizumab (KW-0761) | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 35 | | | |
| Units: Participants | 4 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of patient achieving progression free survival

| | |
|------------------------|---|
| End point title | Number of patient achieving progression free survival |
| End point description: | |

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Disease response was assessed every 8 weeks.

| | | | | |
|-----------------------------|-------------------------|--|--|--|
| End point values | Mogamulizumab (KW-0761) | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 35 | | | |
| Units: participants | 35 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (days)

| | |
|-----------------|-----------------------------|
| End point title | Duration of Response (days) |
|-----------------|-----------------------------|

End point description:

Four subjects had response durations of >1, 43, 77, >539 study days.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Duration of response was measured from the time measurement criteria were met for CR/PR (whichever was first recorded) until the first date that PD or death was objectively documented.

| | | | | |
|-----------------------------|-----------------------------|--|--|--|
| End point values | Mogamulizuma b (KW-0761) | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 35 | | | |
| Units: Days | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From pre-treatment visit until 90 days after the last dose.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|----|
| Dictionary version | 15 |
|--------------------|----|

Reporting groups

| | |
|-----------------------|----------|
| Reporting group title | Baseline |
|-----------------------|----------|

Reporting group description: -

| Serious adverse events | Baseline | | |
|---|------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 18 / 38 (47.37%) | | |
| number of deaths (all causes) | 16 | | |
| number of deaths resulting from adverse events | 2 | | |
| Injury, poisoning and procedural complications | | | |
| Infusion related reaction | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences causally related to treatment / all | 2 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Fall | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vascular disorders | | | |
| Septic shock | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 1 / 1 | | |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |

| | | | |
|--|----------------|--|--|
| Cardiac disorders | | | |
| Stress cardiomyopathy | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac Failure | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nervous system disorders | | | |
| Cerebellar syndrome | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences causally related to treatment / all | 1 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General physical health deterioration | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Asthenia | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Malaise | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Xerosis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| Neutropenia | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Anaemia | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Leukopenia | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Vomiting | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Chronic obstructive pulmonary disease | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Dyspnoea | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory failure | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Skin and subcutaneous tissue disorders | | | |
| Drug eruption | | | |
| subjects affected / exposed | 5 / 38 (13.16%) | | |
| occurrences causally related to treatment / all | 5 / 5 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| Renal impairment | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Pneumonia | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences causally related to treatment / all | 2 / 2 | | |
| deaths causally related to treatment / all | 1 / 1 | | |
| Aspergillosis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cytomegalovirus infection | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|---|----------------|--|--|
| Pneumocystis jiroveci pneumonia | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Sepsis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Sialoadenitis | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lung infection | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Oral infection | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metabolism and nutrition disorders | | | |
| Inappropriate antidiuretic hormone secretion | | | |
| subjects affected / exposed | 1 / 38 (2.63%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

Frequency threshold for reporting non-serious adverse events: 5 %

| | | | |
|---|------------------|--|--|
| Non-serious adverse events | Baseline | | |
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 35 / 38 (92.11%) | | |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|----------------------|--|--|
| Fall subjects affected / exposed occurrences (all) | 2 / 38 (5.26%) 2 | | |
| Infusion related reaction subjects affected / exposed occurrences (all) | 3 / 38 (7.89%) 3 | | |
| Vascular disorders Hypertension subjects affected / exposed occurrences (all) | 2 / 38 (5.26%) 3 | | |
| Hypotension subjects affected / exposed occurrences (all) | 5 / 38 (13.16%) 7 | | |
| Cardiac disorders Tachycardia subjects affected / exposed occurrences (all) | 2 / 38 (5.26%) 2 | | |
| Nervous system disorders Headache subjects affected / exposed occurrences (all) | 4 / 38 (10.53%) 4 | | |
| Lethargy subjects affected / exposed occurrences (all) | 3 / 38 (7.89%) 3 | | |
| Neuropathy peripheral subjects affected / exposed occurrences (all) | 2 / 38 (5.26%) 3 | | |
| Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) | 4 / 38 (10.53%) 6 | | |
| Lymphadenopathy subjects affected / exposed occurrences (all) | 2 / 38 (5.26%) 2 | | |
| Neutropenia subjects affected / exposed occurrences (all) | 3 / 38 (7.89%) 3 | | |

| | | | |
|--|-----------------------|--|--|
| Thrombocytopenia subjects affected / exposed occurrences (all) | 5 / 38 (13.16%) 5 | | |
| General disorders and administration site conditions | | | |
| Asthenia subjects affected / exposed occurrences (all) | 5 / 38 (13.16%) 5 | | |
| Chills subjects affected / exposed occurrences (all) | 3 / 38 (7.89%) 3 | | |
| Fatigue subjects affected / exposed occurrences (all) | 3 / 38 (7.89%) 3 | | |
| Oedema peripheral subjects affected / exposed occurrences (all) | 4 / 38 (10.53%) 7 | | |
| Pyrexia subjects affected / exposed occurrences (all) | 8 / 38 (21.05%) 11 | | |
| Gastrointestinal disorders | | | |
| Abdominal discomfort subjects affected / exposed occurrences (all) | 2 / 38 (5.26%) 2 | | |
| Constipation subjects affected / exposed occurrences (all) | 2 / 38 (5.26%) 2 | | |
| Diarrhoea subjects affected / exposed occurrences (all) | 7 / 38 (18.42%) 10 | | |
| Nausea subjects affected / exposed occurrences (all) | 4 / 38 (10.53%) 6 | | |
| Vomiting subjects affected / exposed occurrences (all) | 5 / 38 (13.16%) 6 | | |
| Respiratory, thoracic and mediastinal disorders | | | |

| | | | |
|---|------------------------|--|--|
| Cough subjects affected / exposed occurrences (all) | 6 / 38 (15.79%) 6 | | |
| Dyspnoea subjects affected / exposed occurrences (all) | 3 / 38 (7.89%) 4 | | |
| Hypoxia subjects affected / exposed occurrences (all) | 2 / 38 (5.26%) 2 | | |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 2 / 38 (5.26%) 2 | | |
| Pleural effusion subjects affected / exposed occurrences (all) | 2 / 38 (5.26%) 2 | | |
| Skin and subcutaneous tissue disorders Drug eruption subjects affected / exposed occurrences (all) | 10 / 38 (26.32%) 18 | | |
| Night sweats subjects affected / exposed occurrences (all) | 2 / 38 (5.26%) 2 | | |
| Pruritus subjects affected / exposed occurrences (all) | 7 / 38 (18.42%) 10 | | |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) | 4 / 38 (10.53%) 5 | | |
| Back pain subjects affected / exposed occurrences (all) | 3 / 38 (7.89%) 3 | | |
| Bone pain subjects affected / exposed occurrences (all) | 2 / 38 (5.26%) 2 | | |
| Infections and infestations | | | |

| | | | |
|-----------------------------------|----------------|--|--|
| Bronchitis | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 3 | | |
| Fungal infection | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |
| Sepsis | | | |
| subjects affected / exposed | 2 / 38 (5.26%) | | |
| occurrences (all) | 2 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---------------|---|
| 05 March 2012 | <ul style="list-style-type: none">• Added only CCR4-positive subjects and the most common PTCL subtypes who expressed the CCR4 target excluding those with indolent disease and/or lower CCR4 expression;• Excluded subjects with a history of moderate or severe psoriasis or with psoriasis associated with systemic symptoms or with a 1st degree relative with history of psoriasis that required medical intervention;• Allowed subjects with known bone marrow involvement to participate if their platelet count was $\geq 75,000$ and allowed for laboratory retesting if the criteria for hematologic, hepatic, and renal function were not met;• Specified that safety surveillance would be performed on a regular basis by the Sponsor and independent therapeutic experts and extended the safety monitoring period from 30 to 90 days after the last dose of study medication;• The subject was required to use contraception for 3 months after the last dose of study drug;• Provided guidelines for documenting and treating a treatment-emergent skin rash;• Incorporated the mSWAT for subjects with skin disease with the IWG response criteria (definitions added) for assessment of global response;• Included the assessment of AEs from the time of informed consent rather than after the first dose of study drug;• Allowed subjects to continue monthly treatment with mogamulizumab, at the discretion of the investigator, beyond CR;• Updated the guidelines for the treatment of hypersensitivity-like reactions;• Allowed skin biopsies for CCR4 expression in subjects with skin disease. |
| 16 April 2013 | <ul style="list-style-type: none">• To modify the Inclusion/Exclusion Criteria;• To increase the number of sites;• To specify the permissible dosing interval for mogamulizumab;• To allow subjects with PD in one disease compartment to continue treatment for a period of up to 8 weeks and allow additional time for the demonstration of an objective response;• To allow subjects who experienced a CR to continue to be treated for a period of 12 months or until progression, whichever occurred first;• To clarify the guidance for the treatment of hypersensitivity-like reactions;• To remove clinical laboratory assessments (i.e., CD4 and CD8 cell counts) not necessary for the conduct of this study.• To lengthen the Screening period;• To clarify the acceptable age of archived lymph node or skin biopsy sample (i.e., collected within 3 months Pretreatment) and to allocate a portion of the sample collected to test a second method of CCR4 analysis in order to establish compatibility between the tests;• To clarify that the SWAT must be performed for all subjects;• To clarify that certain body weight changes requires dose adjustment and to describe the storage conditions of the reconstituted drug product;• To specify that in this study, disease progression and lymphopenia should not be considered adverse events. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported